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Original Article

Observational Study to Assess and Predict Serious Adverse Events after Major Surgery

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Many patients suffer from postoperative serious adverse events (SAEs). Here we sought to determine the incidence of SAEs, assess the accuracy of currently used scoring systems in predicting postoperative SAEs, and determine whether a combination of scoring systems would better predict postoperative SAEs. We prospectively evaluated patients who underwent major surgery. We calculated 4 scores: American Society of Anesthesiologists physical status (ASA-PS) score, the Charlson Score, the POSSUM (Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity) score, and the Surgical Apgar Score (SAS). We assessed the occurrence of SAEs. We assessed the association between each score and SAEs. We combined these scoring systems to find the best combination to predict the occurrence of SAEs. Among 284 patients, 43 suffered SAEs. All scoring systems could predict SAEs. However, their predictive power was not high (the area under the receiver operating characteristic curves [AUROC] 0.6-0.7). A combination of the ASA-PS score and the SAS was the most predictive of postoperative SAEs (AUROC 0.714). The incidence of postoperative SAEs was 15.1%. The combination of the ASA-PS score and the SAS may be a useful tool for predicting postoperative serious adverse events after major surgery.

Key words: serious adverse events, preoperative assessment, intraoperative assessment, ASA-PS, surgical Apgar score

Many patients suffer postoperative serious adverse events (SAEs). Several reports have shown that 10-20% of patients suffer from SAEs after major surgery [1-6]. Once SAEs occur, patient hospital stays are prolonged and patient disability is increased [7,8]. Anesthesiologists should pay more attention to these potentially devastating issues. A systematic approach to predicting, preventing, monitoring, evaluating and treating major adverse events after surgery is required, but such an approach is not currently being used in our region.

To decrease the incidence of SAEs, pre- and intraoperative patient assessments are important tools. Several scoring systems are used to assess pre- and intraoperative patient risks [9]. However, it is not known which scoring system has the best predictive power for determining the risk of postoperative SAEs after major surgery. It is also not known whether a combination of these scoring systems would improve their accuracy. We conducted a prospective observational study to address these questions.

The aims of our study were to (1) determine the incidence of SAEs in a Japanese teaching hospital, (2)

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assess the accuracy of currently used scoring systems to predict postoperative SAEs after major surgery, and (3) determine whether a combination of scoring systems would better predict postoperative SAEs.

Methods

The study was approved by the Institutional Review Board of Okayama University Hospital (No. 462). Written informed consent was obtained from all subjects or a legal surrogate.

Patients. We prospectively evaluated 284 patients who underwent major surgery at Okayama University Hospital in the 7-month period from January to July 2012 (111 females, 173 males; mean age ± SD 61.7 ± 13.9 years). Major surgery was defined as craniotomy, neck surgery, thoracotomy, laparotomy, hip or pelvic surgery, or spinal surgery. We excluded patients under 20 years of age, those having had minor surgery, and those with an operative time less than 2 h. The patient selection is illustrated in Fig. 1.

Preoperative and intraoperative values. We collected patient demographic data from medical records (age, sex, height, weight, operation parts and departments). Surgical characteristics were collected from the case report form written by the anesthetist and the anesthetic records (operative time, anesthetic time, anesthetic method, blood loss, urine output, intravenous fluids, and transfusion).

Calculation of scores. We chose four scores for preoperative and intraoperative assessment: the American Society of Anesthesiologists-Physical Status (ASA-PS) score [10], the Charlson score [11], the Physiological and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) score [12], and the Surgical Apgar Score (SAS) [13]. These 4 scoring systems have different purposes and are used to collect different variables at various times.

The ASA-PS is one of the most widely used and simple preoperative scoring systems. The ASA-PS is intended to classify the preoperative patient status by identifying preoperative comorbidities. The POSSUM scoring system has 2 components: the physiological (PS) component and the operative severity (OS) component. The POSSUM-PS component involves preoperative characteristics such as patient age, cardiac

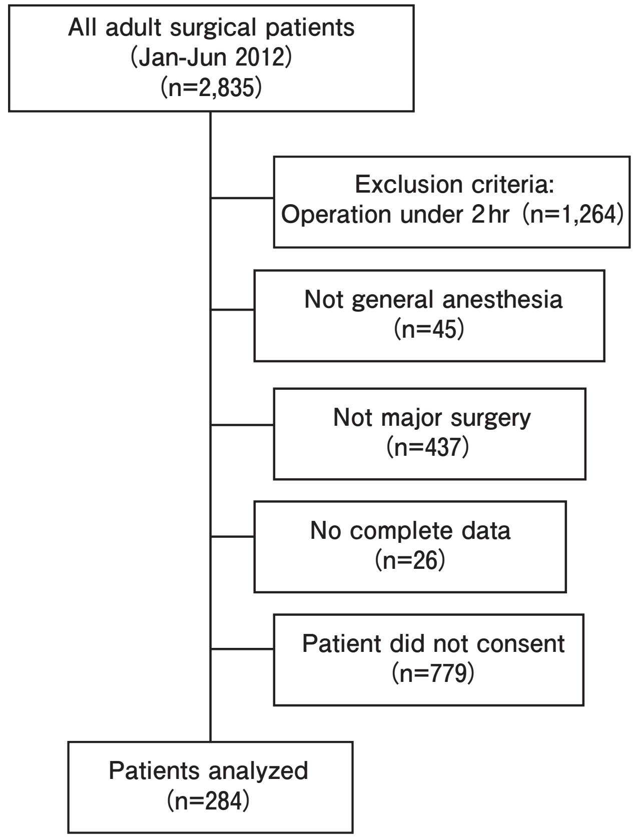

Fig. 1 Patients' flow chart for this study. Among 2,835 adult patients undergoing surgery during study period, we excluded 1,264 patients by exclusion criteria, 779 patients by no consent, etc. Finally, we studied 284 patients who fulfilled our inclusion criteria.

function, and respiratory function, and the POSSUM-OS component reflects the intraoperative evaluation, including the invasiveness of the surgical procedure, the amount of blood loss, malignancy, and urgency.

The Charlson score is a preoperative scoring system. It is not a scoring system for surgical patients, but rather is used to predict 10-year mortality based on comorbid conditions and after 1 year of patients by their complications. We used this standard score as a reference. The SAS is an intraoperative scoring system that was developed to predict morbidity and mortality after surgery using just three intraoperative variables: the lowest mean arterial blood pressure, the blood loss, and the lowest heart rate. Each variable has maximum scores of 3 or 4, and higher scores represents a good condition.

The ASA-PS, Charlson score, and POSSUM-PS include preoperative parameters. The POSSUM-OS and SAS include intraoperative parameters. All required parameters were checked by the attending anesthesiologists, and we calculated the Charlson score, POSSUM, and SAS from these parameters.

Serious adverse events. We sought to monitor 13 SAEs (Table 1) referring to previous reports [1-6]. Postoperative SAEs and the length of hospital stay until hospital discharge or in-hospital death were collected from the electronic medical records kept at our hospital. One of the authors (KS) checked every patient's case notes and evaluated whether or not they had SAEs.

Statistical analyses. All analyses were performed using JMP® Pro statistical software, ver. 10.0.2 (SAS, Cary, NC, USA). For continuous variables, we compared the median values. For variables such as the ASA-PS, Charlson and SAS scores, we created 4 groups for comparison according to the scores' distributions. We assessed the predictive power of each scoring systems by using area under the receiver operating characteristic (AUROC) curves. The data are expressed as means with 95% confidence intervals (CI). A p-value < 0.05 was considered significant. Because the ASA-PS is a standard preoperative assessment tool, we tried to determine the best combination of the ASA-PS system with other scoring systems.

Table 1 The serious adverse events analyzed in this study

Serious adverse event	Definition
Respiratory failure	Requirement of mechanical ventilator support
Tracheostomy	Unscheduled tracheostomy
Pulmonary embolism	Emboli detected by CT scan
Pulmonary edema	Abnormal shadow detected by CT scan or chest x-ray
Acute myocardial infarction	Patients with chest pain or ST-change requiring PCI[a] or medical therapy
Cardiac arrest	Documented pulseless cessation of cardiac output
Deep venous thromboembolism	Emboli detected by CT scan
Acute kidney injury	Requirement of continuous renal replacement therapy
Cerebrovascular disease	Patients with acute neurological symptoms and cerebral infarction or hemorrhage detected by CT or MRI
Severe sepsis	Consensus conference criteria [19]
ICU readmission	Readmission to the ICU
Long ICU stay	ICU stay of more than 2 weeks
Death	Cessation of all vital functions

[a]Percutaneous coronary intervention.

Results

Patient characteristics and SAEs. The flow chart for the patient series is shown in Fig. 1. Among 2,835 adult patients who underwent surgery at our institution during the study period, we studied the 284 patients who fulfilled our inclusion criteria. Our investigation revealed that there were 57 SAEs among 43 patients (15.1%). The patients' characteristics are summarized in Table 2. Their mean age was 61.7 years and the percentage of females was 39.1%. The numbers of gastrointestinal surgeries, liver, biliary, or pancreatic surgeries, urology cases, *etc.* are provided in Table 2.

Of the 43 patients who experienced SAEs, 28 patients (9.86%) suffered from sepsis and 7 patients (2.46%) were readmitted to the ICU. One patient (0.35%) died during the postoperative period (Table 3).

The relationship between the patient baseline characteristics and the SAEs is summarized in Table 4. There were no significant differences in characteristics between patients with and without SAEs. In particular, there was no significant difference in body size between the groups.

Our analysis revealed that the type of anesthesia and types of surgery (thoracotomy and laparotomy) did

Table 2 The patients' characteristics (n = 284)

Age (yrs)	61.7 ± 13.9
Females: males	111 (39.1%): 173 (60.9%)
Height (cm)	160.8 ± 9.6
Weight (kg)	58.7 ± 12.7
BMI	22.6 ± 3.9
No. of patients who underwent:	
Gastrointestinal Surgery	69
Liver, Biliary, Pancreatic Surgery	48
Urology Surgery	39
Respiratory Surgery	36
Neurosurgery	26
Gynecology Surgery	23
Others	43

not affect the incidence of SAEs. Longer operative and anesthesia times were associated with a higher incidence of SAEs. Higher blood loss (>4 ml/kg) during surgery was significantly associated with a higher incidence of SAEs (22.9% vs. 7.64%; $p=0.0004$). Having undergone a transfusion was also associated with a higher incidence of SAEs (Table 5). The length of hospital stay was significantly longer in the SAE (+) group compared to the SAE (−) group (48.56 ± 41.37 days vs. 18.52 ± 13.36 days; $p<0.0001$), as would be expected.

Relationship between postoperative SAEs and pre- and intraoperative scores. As summarized in Table 6, the incidence of SAEs was 8.2% in the group of patients with the ASA-PS score of 1, 12.5% in those with ASA-PS 2, and 29.0% in the patients with ASA-PS 3. There was a significant relationship between the ASA-PS scores and SAEs ($p=0.0055$).

Table 3 Type and incidence of serious adverse events

Serious adverse event	No. (%)
Sepsis	28 (9.86)
ICU readmission	7 (2.46)
PE[a]	4 (1.41)
Respiratory failure	3 (1.05)
DVT[b]	3 (1.05)
CVD[c]	3 (1.05)
Long ICU stay	3 (1.05)
Tracheostomy	1 (0.35)
Pulmonary edema	1 (0.35)
AKI[d]	1 (0.35)
Cardiac arrest	1 (0.35)
AMI[e]	1 (0.35)
Death	1 (0.35)
Total	57

[a]Pulmonary embolism, [b]deep venous thromboembolism, [c] cerebrovascular disease, [d]acute kidney injury, [e]acute myocardial infarction.

Table 4 Patients' baseline characteristics and serious adverse events

		Incidence of SAEs[a]	*p*-value
Age			0.62
	≤ 65 yrs old	25/152 (16.4%)	
	> 65 yrs old	18/132 (13.6%)	
Gender			0.13
	male	31/173 (17.9%)	
	female	12/111 (10.8%)	
Height			0.87
	≤ 160 cm	21/134 (15.7%)	
	> 160 cm	22/150 (14.7%)	
Weight			1
	≤ 60 kg	25/165 (15.2%)	
	> 60 kg	18/119 (15.1%)	
BMI[b] (kg/m^2)			0.87
	≤ 22	21/135 (15.6%)	
	> 22	22/149 (14.8%)	

[a]Serious adverse event, [b]body mass index

Table 5 Patient surgical and anesthetic characteristics and serious adverse events

		Incidence of SAEs[a]	*p*-value
TIVA[a]			0.25
	Yes	7/68 (10.3%)	
	No	36/216 (16.7%)	
Epidural anesthesia			0.17
	Yes	22/173 (12.7%)	
	No	21/110 (19.1%)	
Thoracotomy			0.99
	Yes	8/54 (14.8%)	
	No	35/230 (15.2%)	
Laparotomy			0.86
	Yes	28/178 (15.7%)	
	No	15/106 (14.2%)	
Operative time (min)			0.0015
	≤ 300	13/150 (8.7%)	
	> 300	30/134 (22.4%)	
Anesthesia time (min)			0.0004
	≤ 360	10/138 (7.3%)	
	> 360	33/146 (22.6%)	
Blood loss/body weight (ml/kg)			0.0004
	≤ 4	11/144 (7.64%)	
	> 4	32/140 (22.9%)	
Crystalloids (ml/kg/hr)			0.74
	≤ 7	22/137 (16.1%)	
	> 7	21/147 (14.3%)	
HES[b] (ml/kg)			0.51
	≤ 4	19/142 (13.4%)	
	> 4	24/142 (16.9%)	
RCC[c] (ml/kg)			0.0013
	Yes	15/47 (31.9%)	
	No	28/237 (11.8%)	

[a]Total intravenous anesthesia, [b]hydroxyethyl starch, [c]red cell concentrate.

There were also significant associations between the incidence of SAEs and the POSSUM-OS ($p = 0.0048$), the POSSUM morbidity rate ($p = 0.047$), the POSSUM mortality rate ($p = 0.047$), the Charlson score ($p = 0.011$), and the SAS score ($p = 0.0004$), but not with the POSSUM-PS score ($p = 0.18$).

For each scoring system, we performed a logistic regression analysis and calculated the AUROC curves. The odds ratio of the ASA-PS was 2.21 (1.34–3.73) and the AUROC value was 0.635. Other scores had similar odds ratios (ORs) and AUROC values (Table 7). Because the ASA-PS is a standard preoperative assessment tool, we attempted to identify the best combination of the ASA-PS system with other scoring systems (Table 8), and we found that the ASA-PS and the SAS was the best combination for predicting postoperative SAEs (AUROC 0.714).

Table 6 Scores and serious adverse events

		Incidence of SAEs	*p*-value
ASA-PS[a]			0.0055
	1	5/61 (8.2%)	
	2	20/160 (12.5%)	
	3	18/62 (29.0%)	
	4	0/1	
POSSUM-OS[b,c]			0.0048
	≤16	13/143 (9.1%)	
	>16	30/141 (21.3%)	
POSSUM-PS[b,d]			0.18
	≤16	17/142 (12.0%)	
	>16	26/142 (18.3%)	
POSSUM morbidity rate			0.047
	≤0.48	15/140 (10.7%)	
	>0.48	28/144 (19.4%)	
POSSUM mortality rate			0.047
	≤0.1	15/140 (10.7%)	
	>0.1	28/144 (19.4%)	
Charlson score			0.011
	0–1	6/61 (9.8%)	
	2	14/109 (12.8%)	
	3	5/45 (11.1%)	
	≥4	18/69 (26.1%)	
SAS[e]			0.0004
	1–5	19/71 (26.8%)	
	6	11/59 (18.6%)	
	7	7/78 (9.0%)	
	≥8	6/76 (7.9%)	

[a]American Society of Anesthesiologists physical status, [b]physiological and operative severity score for the enUmeration of mortality and morbidity, [c]operative severity score, [d]physiological score, [e]surgical apgar score.

Discussion

To assess the incidence of SAEs of patients who underwent major surgery in a Japanese teaching hospital, we prospectively studied the cases of 284 such patients, and we found that the incidence of SAEs was 15.1% after major surgery. This number is much higher than we expected. However, other studies have obtained similar numbers in this setting. Bellomo reported that 16.9% of postoperative patients in an Australian teaching hospital experienced at least one

Table 7 Comparison of the scoring systems' likelihood to predict morbidity using odds ratio and receiver operating characteristic curves

	Odds Ratio	*p*-value	AUROC[a]
ASA-PS[b]	2.21 (1.34–3.73)	0.0023	0.635
POSSUM-OS[c,d]	1.08 (1.04–1.12)	<0.0001	0.693
POSSUM-PS[c,e]	1.08 (1.02–1.14)	0.004	0.604
POSSUM morbidity	9.73 (2.91–34.38)	0.0003	0.673
POSSUM mortality	10.62 (3.37–31.69)	<0.0001	0.674
Charlson score	1.21 (1.05–1.40)	0.0085	0.61
SAS[f]	0.63 (0.50–0.78)	<0.0001	0.68

[a]AUROC: Area under the receiver operating characteristic curves, [b]American Society of Anesthesiologists-Physical Status, [c]physiological and operative severity score for the enUmeration of mortality and morbidity, [d]operative severity score, [e]physiological score, [f]surgical apgar score.

Table 8 AUROC[a] curves for each score in combination with ASA-PS score

	AUROC[a]
ASA-PS[b] + POSSUM-OS[c, d]	0.690
ASA-PS + POSSUM-PS[c,e]	0.645
ASA-PS + POSSUM-morbidity	0.678
ASA-PS + POSSUM-mortality	0.677
ASA-PS + Charlson score	0.675
ASA-PS + SAS[f]	0.714

[a]Area under the receiver operating characteristic curves, [b]American Society of Anesthesiologists physical status, [c]physiological and operative severity score for the enUmeration of mortality and morbidity, [d]operative severity score, [e]physiological score, [f]surgical apgar score.

SAE [1], and Vincent reported that 14.1% of patients undergoing general surgery in British hospitals suffered adverse events [4]. We therefore estimate that the worldwide incidence of SAEs after major surgery could be 10% to 15%.

We also analyzed the predictive power of various scoring systems for predicting postoperative serious adverse events. The POSSUM-OS scoring system and the SAS had better predictive power than the others, although their power was approx. 0.7 of the AUROC. Our combination analyses showed that the ASA-PS combined with the SAS had the best predictive power.

We investigated 4 scoring systems: ASA-PS, POSSUM, Charlson and SAS. All of the scores on these systems were significantly different between the patients with SAEs and those without SAEs after major surgery. Among the 4 systems, the POSSUM-OS and the SAS had better predictive power than the others. Only the POSSUM-OS and SAS included intraoperative variables. It seems likely that intraoperative variables would be important for predicting postoperative SAEs.

Regenbogen *et al.* [14] analyzed 4,119 cases of general and vascular surgery, and they reported that the SAS could be effective in identifying a patient's likelihood of experiencing a major complication. The AUROC for detecting SAEs was 0.73 and the incidence of SAEs was 14.1%. Several studies examined the predictive power of the POSSUM scoring system; for example, Hirose *et al.* [15] reported that in 64 spinal surgery patients, the AUROC was 0.588 and the incidence of SAEs was 10.6%. Thorn *et al.* [16] found that the AUROC was 0.76 and the incidence of SAEs was 29% in 101 high-risk surgery patients.

We therefore suspect that the predictive power of scoring systems is heavily dependent on the incidence of SAEs and the characteristics of the patients studied. In our study, the AUROC was approx. 0.7 for both the POSSUM-OS and the SAS, with an incidence of SAEs of 15.1% after major surgery. We believe our findings are highly consistent with those of previous reports.

Because the ASA-PS scoring system is a standard preoperative assessment tool, we sought to determine the best combination of the ASA-PS system with other scoring systems. A combination of the ASA-PS and SAS was the best for predicting postoperative SAEs. To our knowledge, this is the first study to assess the discrimination power of scoring system combinations for predicting postoperative SAEs. As discussed above, the ASA-PS includes only preoperative assessments and the SAS includes intraoperative variables. In our daily practice, anesthesiologists observe patients both preoperatively and intraoperatively. Our combined analysis would be a highly practical way to predict SAEs and would be relevant to clinical decision-making.

There were several limitations in this study. First, this was a retrospective, single-center study. The number of patients was limited. However, our findings of SAEs were similar to those of previous reports, and the scoring systems used are well known and have been used many times. Second, because it is difficult to get informed consent, our cases included just four emergency operations. There was only one death among our 284 patients, though recent publications from the US and Europe showed mortality rates of 3-4% for surgical inpatient mortality [17].

Third, the predictive power of these scoring systems was far from ideal. The AUROCs of the scoring systems in our study were only 0.6-0.7. Fourth, we used very specific definition of SAEs, in accord with previous reports in the field of anesthesia and critical care. Nowadays, the Clavien-Dingo classification [18] and/or Common Terminology Criteria for Adverse Event (Available at http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_8.5x11.pdf) are used widely in the field of surgery. We used our specific definition to compare our incidence of SAEs to that of previous reports in Anesthesiology and Critical Care. Our definition of SAEs made it possible to compare the incidence of SAEs and revealed that the incidence is essentially the same as those reported previously. Fifth, because the SAS has a unique feature in that a higher score represents a better condition, our final multivariate analysis might only reflect this uniqueness of the SAS. However, the combination of ASA-PS and SAS is quite reasonable and easy to implement, reflecting both pre- and intra-operative variables.

In conclusion, our analysis revealed that the incidence of postoperative SAEs after major surgery in a Japanese teaching hospital was 15.1%. A combination of the ASA-PS and the SAS may be useful for predicting postoperative serious adverse events after major surgery. Further investigations are necessary to increase the accuracy of the scoring systems used to predict postoperative SAEs. Such efforts can be expected contribute to improved patient outcomes.

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